Package leaflet: Information for the user

Zolpidemtartraat ratiopharm 5 mg, tabletten
Zolpidemtartraat ratiopharm 10 mg, tabletten

zolpidem tartrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <product name> is and what it is used for

<Product name> is a sleeping tablet belonging to a group of medicines known as benzodiazepine-like agents. It is used for the short-term treatment of sleep disturbances in adults.

<Product name> is only prescribed for sleep disturbances that are severe, disabling or cause extreme distress.

2. What you need to know before you take <product name>

Do not take <product name>:
- if you are **allergic to zolpidem or any of the other ingredients** of this medicine (listed in section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you have ever experienced sleep walking or other behaviours which are unusual while sleeping, (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking <product name> or other medicines containing zolpidem.
- if you suffer from severe muscle weakness (**myasthenia gravis**).
- if your breathing stops for short periods while you are sleeping (**sleep apnoea syndrome**).
- if you suffer from acute and/or severe breathing problems (**respiratory insufficiency**).
- if you suffer from severe liver damage (**hepatic insufficiency**).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking <product name>:

- if you are **elderly or debilitated**.
  You should receive a lower dose (see section 3, How to take <product name>). <product name> has a muscle-relaxant effect. For this reason, especially elderly patients are at risk of falling and consequently of injuries when getting out of bed at night.
- if you have **impaired kidney function**.
  It may take longer for your body to get rid of <product name>. Although no dose adjustment is necessary, caution is required. Contact your doctor.
- if you have **chronic** (long-lasting) **breathing problems**. Your breathing problems could get worse.
- if you have ever had any **heart problems** including slow or uneven heartbeat (long QT syndrome).
- if you have ever had a **mental disorder** or have abused or have been dependent on **alcohol or drugs**. You should be carefully supervised by your doctor during treatment with <product name>, as you are at risk of habituation and psychological dependence.
- if you have **severe liver disease**.
  You may not use <product name> since you are at risk of brain damage (encephalopathy).
  Contact your doctor.
- if you suffer from **delusions (psychoses), depression or anxiety** related to depression, <product name> should not be the only treatment you receive.
- if you had another **mental illness** in the past.
- if you have or have ever **had thoughts of harming or killing yourself**. Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine. However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.
- if you have recently taken zolpidem or other similar medicines for more than four weeks.

General
Before treatment with <product name>:
- the cause of the sleep disturbances should be clarified.
- underlying diseases should be treated.

If treatment of the sleep disturbances is not successful after 7-14 days, this might point to a psychiatric or physical disease which should be checked. You should contact your doctor.

Next-day psychomotor impairment (see also "Driving and using machines")
The day after taking <product name>, the risk of psychomotor impairment, including impaired driving ability may be increased if:

- You take this medicine less than 8 hours before performing activities that require your alertness
- You take a higher dose than the recommended dose
- You take zolpidem while you are already taking another central nervous system depressants or another medicines that increase zolpidem in your blood, or while drinking alcohol, or while taking illicit substances

Take the single intake immediately at bedtime.
Do not take another dose during the same night.

Other considerations
Habituation (habit forming)
If after a few weeks you notice that the tablets are not working as well as they did when first starting treatment, you should go and see your doctor as an adjustment to your dose may be required.

Abuse and/or physical or psychological dependence
Development of physical and psychological dependence is possible.

The risk increases with the dose and duration of treatment and is elevated in patients with a history of mental disorder and/or alcohol, illicit substance or drug abuse. If physical dependence has developed, sudden discontinuation of treatment is accompanied by withdrawal symptoms (see section 3 “If you stop taking <product name>”.

Rebound sleeplessness
On abrupt discontinuation of treatment, inability to sleep may return in a more intensive form. It may be accompanied by mood changes, anxiety and restlessness (see section 3 "If you stop taking product name"

Memory defects (amnesia)
<product name> may cause loss of memory (amnesia). This generally occurs some hours after intake of <product name>. In order to minimise this risk, you should make sure that an uninterrupted sleep of 8 hours will be possible (see section 4, Possible side effects).

Psychiatric and “paradoxical” reactions
Restlessness, inner restlessness, irritability, aggressiveness, delusions (psychoses), rages, nightmares, hallucinations, sleepwalking, inappropriate behaviour, increased sleep disturbances and other adverse behavioural effects are known to occur during treatment.
If this occurs, you should stop taking <product name> and contact your doctor. These reactions are more likely to occur in the elderly.

Sleep walking and other associated behaviours
Sleep walking or other associated behaviours, which are unsusal while sleeping, such as driving, preparing and eating food, making phone calls or having sex, with no recollection of the event have been reported in patients who had taken zolpidem and were not fully awake. The risk of such events may increase if you take <product name> with alcohol or other drugs that slow down central nervous system activity, or if you exceed the maximum recommended dose. If you experience any such event tell your doctor immediately as these sleep behaviours might put you and others at serious risk of injury. Your doctor may recommend that you stop your treatment.

Risk of falling and severe injuries
<Product name> can cause drowsiness and decrease your level of alertness. This could cause you to fall, sometimes leading to severe injuries.

Children and adolescents
<Product name> is not recommended for use in children and adolecents under 18 years of age.

Other medicines and <product name>
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines. This includes medicines you buy without a prescription, including herbal medicines.
Other medicines may be affected by <product name>. They, in turn, may affect how well <product name> works.

While taking <product name> with the following medicines, drowsiness and next-day psychomotor impairment effects, including impaired driving ability, may be increased:

- medicines for some mental health problems (antipsychotics)
- medicines for sleep problems (hypnotics)
- medicines to calm or reduce anxiety
- muscle relaxants (e.g. baclofen), as their muscle relaxing effect may be increased
- medicines for depressions
- medicines for moderate to severe pain (narcotic analgesics)
- medicines for epilepsy
- medicines used for anaesthesia
- medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines)

Concomitant use of <product name> and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
However if your doctor does prescribe <product name> together with opioids the dose and duration of concomitant treatment should be limited by your doctor.
Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

<product name> can interact with medicines to treat a variety of fungal infections such as itraconazole and ketoconazole. Taking ketoconazole with <product name> may increase the drowsiness effect.

While taking <product name> with antidepressants including bupropion, desipramine, fluoxetine, sertraline and venlafaxine, you may see things that are not real (hallucinations).

It is not recommended to take <product name> with fluvoxamine or ciprofloxacin.

Medicines which strongly enhance the activity of certain liver enzymes can possibly reduce the effect of <product name> e.g. rifampicin (an **antibacterial** used to treat infections), carbamazepine and phenytoin (medicines used for example for epilepsy) and St.John`s Wort (a herbal medicine for mood swings and depression).Concomitant use is not recommended.

<product name> with alcohol
Do not drink any **alcohol** during treatment. Alcohol can increase the effects of zolpidem and make you sleep very deeply so that you do not breathe properly or have difficulty waking.
Drinking alcohol during treatment can influence the ability to drive or use machinery.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
<product name> should **not be taken during pregnancy**, especially not in the first three months of pregnancy.

If used during pregnancy, there is a risk that the baby is affected.
Some studies have shown that there may be an increased risk of cleft lip and palate (sometimes called "harelip") in the newborn baby.

Reduced fetal movement and fetal heart rate variability may occur after taking zolpidem during the second and/or third trimester of pregnancy.
If zolpidem is taken at the end of pregnancy or during labour, your baby may show muscle weakness, a drop in body temperature, difficulty feeding and breathing problems (respiratory depression).

If <product name> is taken for a longer period in late pregnancy, your baby may develop physical dependence and may be at risk of developing withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

Breast-feeding
Since zolpidem passes into mother's milk in low quantities, <product name> should **not be taken during breast-feeding**.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

<product name> has major influence on the ability to drive and use machines such as “sleep driving”. On the day after taking <product name> (as other hypnotic medicines), you should be aware that:

- You may feel drowsy, sleepy, dizzy or confused
- Your quick decision-making may be longer
- Your vision may be blurred or double
- You may be less alert

A period of at least 8 hours is recommended between taking <product name> and driving, using machinery and working at heights to minimize the above listed effects.
Do not drink alcohol or take other psychoactive substances while you are taking <product name>, as it can increase the above listed effects
For more information about possible side effects which could affect your driving see section 4 of this leaflet.

<product name> contains lactose.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

<product name> contains sodium.
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

3. How to take <product name>

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

<product name> should be taken:

- as a single intake.
- just before bedtime.
- Make sure you have a period of at least 8 hours after taking this medicine before performing activities that require your alertness.
- Do not exceed 10mg per 24 hours.
- Take this medicine by mouth.
- Swallow the tablet with liquid.

The recommended daily dose is:

Adults
The recommended dose per 24 hours is 10 mg zolpidem tartrate. A lower dose may be prescribed to some patients.

Elderly (over 65 years), debilitated patients or patients with mild to moderate liver impairment
A lower dose of 5 mg zolpidem tartrate per day is recommended at the start of treatment. Your doctor may increase your dose to 10 mg if the effect is insufficient and the medicinal product is tolerated well.

Use in children and adolescents
<product name> is not recommended for use in children and adolescents under 18 years of age.

Maximum dose
Do not exceed 10 mg zolpidem tartrate per 24 hours.

Duration of treatment
After repeated intake over several weeks the sleep-promoting (hypnotic) effect can be reduced.

The duration of treatment should be as short as possible. This could be a few days up to 2 weeks, and should not be longer than four weeks the stepwise withdrawal phase included.

In certain situations you may be required to take <product name> for longer. Your doctor will tell you when and how to stop treatment.

If you take more <product name> than you should
Contact your doctor immediately or go to a hospital casualty department straight away. Do not go unaccompanied to the hospital, ask another person to go with you. Take the medicine pack, this leaflet and any leftover tablets with you. This is so the doctor knows what you have taken.
Taking too much zolpidem can be very dangerous. The following effects may happen: feeling drowsy, confused, sleeping deeply and possibly falling into a fatal coma.

If you forget to take <product name>
Do not take a double dose to make up for a forgotten dose. If you are still able to sleep 8 hours, you can take the tablet. If this is not possible, do not take the tablet until you go to bed the following day.

If you stop taking <product name>
Keep taking <product name> until your doctor tells you to stop. Do not stop taking <product name> suddenly, but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over a period of time.
If you stop taking <product name> suddenly, your sleep problems may come back and you may get a 'withdrawal effect'. If this happens you may get some of the effects listed below.
See a doctor straight away if you get any of the following effects:
- Feeling anxious, restless, irritable or confused
- Headache
- Faster heartbeat or uneven heartbeat (palpitations)
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Being more sensitive to light, noise and touch than normal
- Relaxed grip on reality
- Feeling distant from your body or feeling 'puppet-like'
- Numbness and tingling in your hands and feet
- Aching muscles
- Stomach problems
- Sleep problems come back worse than before
- In rare cases fits (seizures) may also occur.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

These effects seem to be related to individual sensitivity and seem to appear more often within the hour after taking the tablet if you do not go to bed or you do not sleep immediately.

These side effects occur most frequently in elderly patients.

Stop taking <product name> and see a doctor or go to a hospital straight away if:
- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue which can be life threatening if throat swelling blocks the airway (angiooedema). The frequency of this side effect is not known (frequency cannot be estimated from the available data).

The other side effects are:

Common (may affect up to 1 in 10 people)

- sensing things that are not real (hallucinations), agitation, nightmares
- depression
- sleepiness during the following day, numbed emotions, reduced alertness, tiredness, headache, dizziness, difficulty remembering things (amnesia), which may be associated with inappropriate behaviour (see section 2, warnings and precautions), memory impairment, inability to recall the recent past (anterograde amnesia), ataxia (loss of coordination of the muscles), worsening insomnia
- sensation of spinning with loss of balance (vertigo)
- infection of the lungs or airways (respiratory infection)
- diarrhoea, feeling sick (nausea), vomiting, stomach pain
- back pain
- fatigue

Uncommon (may affect up to 1 in 100 people)

- state of confusion, irritability
- sleep walking or other associated behaviours, which are unsusal while sleeping, such as driving, preparing and eating food, making phone calls or having sex
- feeling of intense elation or confidence (euphoria), feeling restless or angry
- speech difficulties, disturbance in attention, tremor
- double vision, blurred vision
- change in appetite (appetite disorder)
- increased liver enzymes
- unusual sensation or tingling of skin, itching skin or skin rash, excessive sweating
- pain in your joints or muscles, muscle spasms, weak muscles, neck pain

Rare (may affect up to 1 in 1000 people)

- change in sex drive (libido)
- liver injury (hepatocellular, cholestatic or mixed)
- hives
- abnormal posture when walking (abnormal gait)

Very rare (may affect up to 1 in 10000 people)

- decreased ability to see (visual impairment)
- physical or psychological dependence. If you suddenly stop taking <product name>, you may suffer from withdrawal symptoms (see section 2, Warnings and precautions), thinking things that are not true (delusions)
- slower breathing (respiratory depression)

Not known (frequency cannot be estimated from the available data)

- a drug effect that is opposite to what would be usually expected (paradoxical reaction), abnormal behaviour, mental disturbances(psychosis), anger, such reactions are more likely to occur in the elderly
- misuse of <product name> by drug abusers has been reported, being less aware of your environment
- drug tolerance, falls (mainly in elderly patients and when <product name> was not taken as prescribed)
- delirium (a sudden and severe change in mental state that causes a person to appear confused or disoriented)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store <product name>

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <product name> contains

The active substance is 5 mg zolpidem tartrate
The active substance is 10 mg zolpidem tartrate

The other ingredients are
Tablet core: Lactose monohydrate, microcrystalline cellulose, sodium starch glycollate (Type A), magnesium stearate, hypromellose
Tablet coating: Hypromellose, macrogol 400, titanium dioxide (colouring agent E 171)

What <product name> looks like and contents of the pack
<*product name*> *5 mg film-coated tablets* are white, oval, biconvex and embossed with "ZIM" on one side and "5" on the other side.
<*product name*> *10 mg film-coated tablets* are white, oval, biconvex with a break score and embossed with "ZIM" and "10" on one side. The tablet can be divided into equal doses.

The film-coated tablets are packed in blisters in a carton containing 4, 5, 7, 10, 14, 15, 20, 28, 30, 50, 100, 500 film-coated tablets.
<*product name*> *filmcoated tablets* are also available in tablet containers with 30, 100, 500 tablets, sealed with a child proof closure.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Ratiopharm GmbH
Graf-Arco-Str. 3
89079 Ulm
Duitsland

Fabrikant
Merckle GmbH
Ludwig-Merckle-Strasse 3
D-89143 Blaubeuren
Duitsland

In het register ingeschreven onder
RVG 25110 - tabletten, 5 mg
RVG 25111 - tabletten, 10 mg

Dit geneesmiddel is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Zolpidemtartrate 5 mg film-coated tablets	
Duitsland	Zolpidem-ratiopharm 5 mg Filmtabletten
Nederland	Zolpidemtartraat ratiopharm 5 mg, tabletten
Zweden	Zolpidem ratiopharm 5 mg filmdragerade tabletter
Zolpidemtartrate 10 mg film-coated tablets	
Oostenrijk	Zolpidem ratiopharm 10 mg - Filmtabletten
Duitsland	Zolpidem-ratiopharm 10 mg Filmtabletten
Nederland	Zolpidemtartraat ratiopharm 10 mg, tabletten
Portugal	Zolpidem-ratiopharm 10 mg comprimidos revestidos
Spanje	Zolpidem ratiopharm 10mg comprimidos recubiertos EFG
Zweden	Zolpidem ratiopharm 10 mg filmdragerade tabletter

Deze bijsluiter is voor het laatst goedgekeurd in juni 2024.